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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

1

of

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## Complete if Known

Application Number	10/618,531
Filing Date	07-11-2003
First Named Inventor	Phillip A. Furman
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	04674.105070 TRI 1016

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## U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
DJ	AA	3,798,209		Witkowski <i>et al.</i>	03-19-1974	
	AB	RE29,835		Witkowski <i>et al.</i>	11-14-1978	
	AC	5,075,445		Jarvest <i>et al.</i>	12-24-1991	
	AD	5,142,051	A	Holy <i>et al.</i>	08-25-1992	
	AE	5,444,063	A	Schinazi	08-22-1995	
	AF	5,539,116	A	Liotta <i>et al.</i>	07-23-1996	
	AG	5,565,438	A	Chu <i>et al.</i>	10-15-1996	
	AH	5,567,688	A	Chu <i>et al.</i>	10-22-1996	
	AI	5,587,362	A	Chu <i>et al.</i>	12-24-1996	
	AJ	5,641,763	A	Holy <i>et al.</i>	06-24-1997	
	AK	5,674,841	A	Pragnell <i>et al.</i>	10-07-1997	
	AL	5,674,849	A	Twist <i>et al.</i>	10-07-1997	
	AM	5,684,010	A	Schinazi <i>et al.</i>	11-04-1997	
	AN	5,684,153	A	Geen <i>et al.</i>	11-04-1997	
	AO	5,703,058	A	Schinazi <i>et al.</i>	12-30-1997	
	AP	5,767,102	A	Draper <i>et al.</i>	06-16-1998	
	AQ	5,767,122	A	Chu <i>et al.</i>	06-16-1998	
	AR	5,808,040	A	Chu <i>et al.</i>	09-15-1998	
	AS	5,814,639	A	Liotta <i>et al.</i>	09-29-1998	
	AT	5,834,474	A	Schinazi	11-10-1998	
	AU	5,905,070	A	Schinazi <i>et al.</i>	05-18-1999	
	AV	5,914,331	A	Liotta <i>et al.</i>	06-22-1999	
	AW	5,990,093	A	Schinazi <i>et al.</i>	11-23-1999	
	AX	6,194,388	B1	Krieg <i>et al.</i>	02-27-2001	
	AY	6,194,391	B1	Schinazi <i>et al.</i>	02-27-2001	
	AZ	6,207,646	B1	Krieg <i>et al.</i>	03-27-2001	
	AAA	6,218,371	B1	Krieg <i>et al.</i>	04-17-2001	
	AAB	6,225,292	B1	Raz <i>et al.</i>	05-01-2001	
	AAC	6,232,300	B1	Schinazi <i>et al.</i>	05-15-2001	
	AAD	6,239,116	B1	Krieg <i>et al.</i>	05-29-2001	
DJ	AAE	6,339,068	B1	Krieg <i>et al.</i>	01-15-2002	

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Signature

/Donna Jagoe/ (09/30/2006)

Date

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Sheet 2 of 7

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Application Number 10/618,531  
Filing Date 07-11-2003  
First Named Inventor Phillip A. Furman  
Group Art Unit Unassigned  
Examiner Name Unassigned  
Attorney Docket Number 04674.105070 TRI 1016 US

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		Number	Kind Code <sup>2</sup> (if known)			
DJ	BA	6,406,705	B1	Davis <i>et al.</i>	06-18-2002	
	BB	6,562,798	B1	Schwartz	05-13-2003	
	BC	6,589,940	B1	Raz <i>et al.</i>	07-08-2003	
	BD	20020098199	A1	Van Nest <i>et al.</i>	07-25-2002	
DJ	BE	20030091599	A1	Davis <i>et al.</i>	05-15-2003	

## FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number	Kind Code <sup>2</sup> (if known)				
DJ	BF	DE	4,224,737	A1	Herbert Schott	02-03-1994		
	BG	EPA	0,494,119	A1	IAF Biochem Int'l.	08-07-1992		
	BH	WO	92/18517	A1	Yale Univ.; U. Ga. R. F.	10-29-1992		
	BI	WO	94/09793	A1	Emory University	05-11-1994		
	BJ	WO	95/07086	A1	Emory Univ.; CNRS; UAB R.F.	03-16-1995		
	BK	WO	95/07287	A1	CNRS	03-16-1995		
	BL	WO	95/20595	A1	U. Ga. Res. Found.; Yale Univ.	08-03-1995		
	BM	WO	95/32984	A1	Boehringer Mannheim	12-07-1995		
	BN	WO	96/13512	A2	Genencor International	05-09-1996		
	BO	WO	96/22778	A2	Emory University	08-01-1996		
	BP	WO	96/40164	A1	Emory; UAB Res. F.; CNRS	12-19-1996		
	BQ	WO	97/28259	A1	University of California	08-07-1997		
	BR	WO	98/16247	A1	University of California	04-23-1998		
	BS	WO	98/23285	A1	SmithKline Beecham	06-04-1998		
	BT	WO	98/55495	A2	Dynavax Technologies	12-10-1998		
	BU	WO	99/05157	A1	Univ. of Georgia Res. Found.	02-04-1999		
	BV	WO	99/05158	A1	Univ. of Georgia Res. Found.	02-04-1999		
	BW	WO	99/11275	A2	University of California	03-11-1999		
	BX	WO	99/62923	A2	Dynavax Technologies	12-09-1999		
DJ	BY	WO	99/66936	A1	Emory; Novirio Pharm. (Idenix)	12-20-1999		

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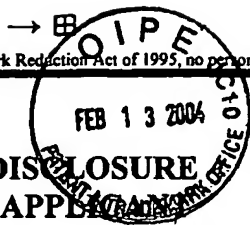
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First Named Inventor	Phillip A. Furman
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	04674.105070 TRI 1016 US

Sheet 3 of 7

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## **FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>2</sup>	Number	Kind Code <sup>3</sup> (if known)				
DJ	CA	WO	00/16804	A1	Dynavax Technologies	03-30-2000		
	CB	WO	00/09531	A2	Novirio Pharm. (Idenix), CNRS	02-24-2000		
	CC	WO	00/21556	A1	Dynavax Technologies	04-20-2000		
	CD	WO	00/25797	A1	Triangle Pharmaceuticals	05-11-2000		
	CE	WO	01/12223	A2	Dynavax Technologies	02-22-2001		
	CF	WO	01/22972	A2	U. Iowa R.F.; Coley Pharm.	04-05-2001		
	CG	WO	01/22990	A2	Coley Pharm.; U. Iowa R.F.	04-05-2001		
	CH	WO	01/68077	A2	Dynavax Technologies	09-20-2001		
	CI	WO	01/68078	A2	Dynavax Technologies	09-20-2001		
	CJ	WO	01/68116	A2	Dynavax Technologies	09-20-2001		
	CK	WO	01/68117	A2	Dynavax Technologies	09-20-2001		
	CL	WO	01/68143	A2	Dynavax Technologies	09-20-2001		
	CM	WO	01/68144	A2	Dynavax Technologies	09-20-2001		
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	CP	WO	02/052002	A2	Dynavax Technologies	07-04-2002		
	CQ	WO	02/068058	A2	Triangle Pharmaceuticals	09-06-2002		
	CR	WO	02/069369	A2	Coley Pharmaceutical	09-06-2002		
	CS	WO	02/079213	A1	Triangle Pharmaceuticals	10-10-2002		
	CT	WO	03/000922	A2	Dynavax Technologies	01-03-2003		
	CU	WO	03/012061	A2	Coley Pharm.; Max Delbruck C.	02-13-2003		
	CV	WO	03/014316	A2	Dynavax Technologies	02-20-2003		
	CW	WO	03/015711	A2	Coley Pharmaceutical	02-27-2003		
DJ	CX	WO	03/031573	A2	Coley Pharmaceutical	04-17-2003		

Examiner Signature	/Donna Jagoe/ (09/30/2006)	Date Considered	
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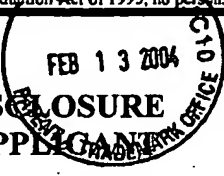
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number Filing Date First Named Inventor Group Art Unit Examiner Name Attorney Docket Number	10/618,531 07-11-2003 Phillip A. Furman Unassigned Unassigned 04674.105070 TRI 1016 US
Sheet	4	of	7

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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>	
DJ	DA	AGUESSE-GERMON, <i>et al.</i> , "Inhibitory effect of 2'-fluoro-5-methyl-b-L-arabinofuranosyl-uracil on duck hepatitis B virus replication," <i>Antimicrob. Agents Chemother.</i> , 42(2):369-376 (February 1998).		
	DB	AHMED, S.N.S., <i>et al.</i> , "Early detection of viral resistance by determination of hepatitis B virus polymerase mutations in patients treated by lamivudine for chronic hepatitis B," <i>Hepatology</i> , 32(5):1078-1088 (November 2000)		
	DC	ALLEN, M. I., <i>et al.</i> , "Identification and characterization of mutations in hepatitis B virus resistant to lamivudine," <i>Hepatology</i> 27(6):1670-1677 (June 1998).		
	DD	BALLAS, Z.K., <i>et al.</i> , "Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA," <i>The Journal of Immunology</i> , 157:1840-1845 (1996).		
	DE	CHAYAMA, K., <i>et al.</i> , "Emergence and takeover of YMDD motif mutant hepatitis B virus during long-term lamivudine therapy and re-takeover by wild type after cessation of therapy," <i>Hepatology</i> 27(6):1711-1716 (June 1998).		
	DF	CHANG, C.-N., <i>et al.</i> , "Deoxycytidine deaminase-resistant stereoisomer is the active form of (+)-2'-3'-dideoxy-3'-thiacytidine in the inhibition of hepatitis B virus replication," <i>Journal of Biological Chemistry</i> , 267(20):13938-13942 (1992).		
	DG	CHIN, R., <i>et al.</i> , "In vitro susceptibilities of wild-type or drug-resistant hepatitis B virus to (-)-β-D-2,6-diaminopurine dioxolane and 2'-fluoro-5-methyl-β-L-arabinofuranosyluracil," <i>Antimicrob. Agents Chemother.</i> , 45(9):2495-2501 (September 2001).		
	DH	CHOW, Y.-K., <i>et al.</i> , "Use of evolutionary limitations of HIV-1 multidrug resistance to optimize therapy," <i>Nature</i> , 361:650-654 (1993).		
	DI	COLLEDGE, D., <i>et al.</i> , "Synergistic inhibition of hepadnaviral replication by lamivudine in combination with penciclovir <i>in vitro</i> ," <i>Hepatology</i> 26(1):216-225 (July 1997).		
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	DK	COWDERY, J.S., <i>et al.</i> , "Bacterial DNA induces NK cells to produce IFN-γ <i>in vivo</i> and increases the toxicity of lipopolysaccharides," <i>J. Immunol.</i> , 156:4570-4575 (1996).		
	DL	CULLEN, J.M., <i>et al.</i> , "In vivo antiviral activity and pharmacokinetics of (-)-cis-5-fluoro-1-(2-(hydroxymethyl)-1,3-oxathiolan-5-yl)cytosine in woodchuck hepatitis virus-infected woodchucks" <i>Antimicrob. Agents Chemother.</i> 41(10):2076-2082 (October 1997).		
DJ	DM	DU, J., <i>et al.</i> , "A practical synthesis of L-FMAU from L-arabinose," <i>Nucleosides and Nucleosides</i> , 18(2):187-195 (1999).		

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Sheet **5** of **7**

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Application Number	<b>10/618,531</b>
Filing Date	<b>07-11-2003</b>
First Named Inventor	<b>Phillip A. Furman</b>
Group Art Unit	<b>Unassigned</b>
Examiner Name	<b>Unassigned</b>
Attorney Docket Number	<b>04674.105070 TRI 1016 US</b>

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## **OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

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DJ	EA	FURMAN et al., "The Anti-Hepatitis B Virus Activities, Cytotoxicities, and Anabolic Profiles of the (-) and (+) Enantiomers of <i>cis</i> -5-Fluoro-1-{2-(Hydroxymethyl)-1,3-oxathiolane-5-yl}-Cytosine" <i>Antimicrobial Agents and Chemotherapy</i> , 36(12):2686-2692 (December 1992).	
	EB	GÁLVEZ, J., et al., "Topological approach to analgesia," <i>J. Chem. Inf. Comput. Sci.</i> , 35(5):1198-1203 (1994).	
	EC	GISH, R.G., et al., "Dose range study of pharmacokinetics, safety, and preliminary antiviral activity of emtricitabine in adults with hepatitis B virus infection," <i>Antimicrob. Agents Chemother.</i> , 46(6):1734-1740 (June 2002).	
	ED	GUIDOTTI, L.G., et al., "Noncytopathic clearance of lymphocytic choriomeningitis virus from the hepatocyte," <i>J. Exp. Med.</i> , 189:1555-1564 (1999).	
	EE	GUO, J.-T., et al., "Apoptosis and regeneration of hepatocytes during recover from transient hepadnavirus infections" <i>J. Virol.</i> , 74:1495-1505 (2000).	
	EF	KLINMAN, D.M., et al., "Contribution of CpG motifs to the immunogenicity of DNA vaccines," <i>J. Immunol.</i> , 158(8):3635-3639 (April 15, 1997).	
	EG	KORBA, B.E., et al., "Enhanced antiviral benefit of combination therapy with lamivudine and famciclovir against WHV replication in chronic WHV carrier woodchucks," <i>Antivir. Res.</i> 45:19-32 (2000).	
	EH	KORBA, B.E., et al., "Effect of oral administration of emtricitabine on woodchuck hepatitis virus replication in chronically infected woodchucks," <i>Antimicrob. Agents Chemother.</i> 44(6):1757-1760 (June 2000).	
	EI	KRIEG, A.M., "Leukocyte stimulation by oligodeoxynucleotides," Chapter 24 in <i>Applied Antisense Oligonucleotide Technology</i> , C.A. Stein and A.M. Krieg, Eds., Wiley-Liss, Publishers, New York (1998), pp. 431-448.	
	EJ	LEUNG, N. W., et al., "Extended lamivudine treatment in patients with chronic hepatitis B enhances hepatitis B e antigen seroconversion rates: Results after 3 years of therapy," <i>Hepatology</i> 33(6):1527-1532 (June 2001).	
	EK	LIN, T.-S., et al., "Synthesis and antiviral activity of various 3'-azido analogues of pyrimidine deoxyribonucleosides against human immunodeficiency virus (HIV-1, HTLV-III/LAV), <i>J. Med. Chem.</i> , 31(2):336-340 (1988).	
DJ	EL	LIPFORD, G.B., et al., "CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: A new class of vaccine adjuvants," <i>Eur. J Immunol.</i> 27:2340-2344 (1997).	

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Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	04674.105070 TRI 1016 US

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## **OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
DJ	FA	LOK, A.S.F., and McMAHON, B.J., "Chronic Hepatitis B," AASLD Practice Guidelines, in <i>Hepatology</i> , 1225-1241 (December 2001).	
	FB	MAHMOUDIAN, M., "Quantitative structure-activity relationships (QSARs) of pyrimidine nucleosides as HIV-1 antiviral agents," <i>Pharm. Research</i> , 8(1):43-46 (1991).	
	FC	MASON, W.S., <i>et al.</i> , "Lamivudine therapy of WHV-infected woodchucks," <i>Virology</i> , 245:18-32 (1998).	
	FD	MELEGARI, M., <i>et al.</i> , "Hepatitis B virus mutants associated with 3TC and famciclovir administration are replication defective," <i>Hepatology</i> 27(2):628-633 (February 1998).	
	FE	MENNE, S., <i>et al.</i> , "Immunization with surface antigen vaccine alone and after treatment with 1-(2-fluoro-5-methyl-β-L-arabinofuranosyl)-uracil (L-FMAU) breaks humoral and cell-mediated immune tolerance in chronic woodchuck hepatitis virus infection," <i>J. Virology</i> , 76(11):5305-5314 (June 2002).	
	FF	NOWAK, M.A., <i>et al.</i> , "Viral dynamics in hepatitis B virus infection," <i>Proc. Natl. Acad. Sci. USA</i> 93:4398-4402 (April 1996).	
	FG	ONO, S. K., <i>et al.</i> , "The polymerase L528M mutation cooperates with nucleotide binding-site mutations, increasing hepatitis B virus replication and drug resistance," <i>J. Clin. Investig.</i> , 107:449-455 (2001).	
	FH	PEEK <i>et al.</i> , "Antiviral activity of clevudine [L-FMAU, (1(2-fluoro-5-methyl-beta, L-arabinofuranosyl) uracil)] against woodchuck hepatitis virus replication and gene expression in chronically infected woodchucks ( <i>Marmota monax</i> )" <i>Hepatology</i> 2001, 33, 254-66.	
	FI	PISETSKY, D.S., "The immunological properties of DNA," <i>The Journal of Immunology</i> , 156:421-423 (1996).	
	FJ	RISTIG, M.B., <i>et al.</i> , "Tenofovir disoproxil fumarate therapy for chronic hepatitis B in Human Immunodeficiency Virus / Hepatitis B Virus-coinfected individuals for whom interferon-α and lamivudine therapy have failed," <i>J. Infectious Diseases</i> , 186:1844-1847 (December 15, 2002).	
	FK	ROMAN, M., <i>et al.</i> , "Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants," <i>Nature Med.</i> , 3(8):849-854 (August 1997).	
	FL	SATO, Y., <i>et al.</i> , "Immunostimulatory DNA sequences necessary for effective intradermal gene immunization," <i>Science</i> , 273(5273):352-354 (July 19, 1996).	
	FM	SEIGNE'RES, B., <i>et al.</i> , "Inhibitory activity of dioxolane purine analogs on wild-type and lamivudine-resistant mutants of hepadnaviruses," <i>Hepatology</i> 36(3):710-722 (September 2002).	
DJ	FN	SEIGNE'RES, B., <i>et al.</i> , "Evolution of Hepatitis B virus polymerase gene sequence during famciclovir therapy for chronic hepatitis B," <i>J. Infect. Dis.</i> , 181:1221-1233 (April 2000).	

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Signature

/Donna Jagoe/ (09/30/2006)

Date

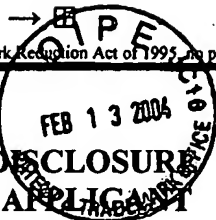
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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### Complete if Known

Application Number	10/618,531
Filing Date	07-11-2003
First Named Inventor	Phillip A. Furman
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	04674.105070 TRI 1016 US

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DJ	GA	SEIGNE'RES, B., <i>et al.</i> , "Duck hepatitis B virus polymerase gene mutants associated with resistance to lamivudine have a decreased replication capacity in vitro and in vivo," <i>J. Hepatol.</i> 34:114-122 (2001).	
	GB	SEIGNÈRES, B., <i>et al.</i> , "Effects of pyrimidine and purine analog combinations in the duck Hepatitis B Virus infection model," <i>Antimicrobial Agents and Chemotherapy</i> , 47(6):1842-1852 (2003).	
	GC	SHIMADA, S., <i>et al.</i> , "In vivo augmentation of natural killer cell activity with a deoxyribonucleic acid fraction of BCG," <i>Jpn. J. Cancer Res (Gann)</i> , 77:808-816 (August 1986).	
	GD	SNYDER, S., <i>et al.</i> , "The triple combination indinavir-zidovudine-lamivudine is highly synergistic," <i>Antimicrob. Agents Chemother.</i> , 44(5):1051-1058 (April 2000).	
	GE	STUYVER, L. J., <i>et al.</i> , "Nomenclature for antiviral-resistant human hepatitis B virus mutations in the polymerase region," <i>Hepatology</i> 33(3):751-757 (March 2001).	
	GF	TSAL, C.-H., <i>et al.</i> , "Effect of anti-HIV 2'-b-fluoro-2',3'-dideoxynucleoside analogs on the cellular content of mitochondrial DNA and on lactate production," <i>Biochem. Pharmacol.</i> , 48(7):1477-1481 (1994).	
	GG	VILLAHERMOSA, M. L., <i>et al.</i> , "Synergistic inhibition of HIV-1 reverse transcriptase by combinations of chain-termination nucleotides," <i>Biochemistry</i> 36:13223-13231 (1997).	
	GH	Von JANTA-LIPINSKI, M., <i>et al.</i> , "Newly synthesized L-enantiomers of 3'-fluoro-modified β-2'-deoxyribonucleoside 5'-triphosphates inhibit hepatitis B DNA polymerases but not the five cellular DNA polymerases α, β, γ, δ, and ε nor HIV-1 reverse transcriptase," <i>J. Med. Chem.</i> , 41(12):2040-2046 (1998).	
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	GJ	YING, C., <i>et al.</i> , "Inhibition of the replication of the DNA polymerase M550V mutation variant of human Hepatitis B Virus by adefovir, tenofovir, L-FMAU, DAPD, penciclovir and lobucavir," <i>J. Viral Hepatitis</i> , 7:161-165 (2000).	
↓	GK	ZHU, Y., <i>et al.</i> , "Kinetics of hepadnavirus loss from the liver during inhibition of viral DNA synthesis" <i>J. Virol.</i> , 75(1):311-22 (2001).	
DJ	GL	ZOULIM, F., "Evaluation of novel strategies to combat hepatitis B virus targeting [sic] wild-type and drug-resistant mutants in experimental models," <i>Antivir. Chem. Chemother.</i> , 12(Suppl. 1):131-142 (2001).	

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Examiner Signature	/Donna Jagoe/ (09/30/2006)	Date Considered	
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<b>Filing Date</b>	<b>07-11-2003</b>
<b>First Named Inventor</b>	<b>Phillip A. Furman</b>
<b>Group Art Unit</b>	<b>Unassigned</b>
<b>Examiner Name</b>	<b>Unassigned</b>
<b>Attorney Docket Number</b>	<b>04674.105070 (TRI 1016 US)</b>

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		Number	Kind Code <sup>2</sup> (if known)			
DJ		5,486,520		Belleau et al.	1/23/96	
DJ		5,145,677		Von Eichborn et al.	9/8/92	

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